

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

APPLICANT: NAKAZATO, Tokiya

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EXAMINER: Vathyam, S.

TITLE: AUTOMATIC IN SITU ELECTROPHORESIS METHOD AND APPARATUS

Amendment A: REMARKS

Upon entry of the present amendments, Claims 1-39 have been canceled and Claims 40-73 have been substituted therefor. Reconsideration of the rejections, in light of the forgoing amendments and present remarks, is respectfully requested. The present amendments have been entered for the purpose of more clearly distinguishing the present invention from the prior art and for the purpose of placing the claims into a condition for allowance.

In the Office Action, it was indicated that Claims 1, 7-11, 16-18, 21, 24-25, 29-30 and 34-36 were rejected under 35 U.S.C. § 102 as being anticipated by the Sarrine patent. Claim 2 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Sarrine patent in view of the Warren patent. Claims 3-6 and 27-28 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Sarrine patent in view of the Cathcart patent. Claims 12-15 and 31-33 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Sarrine patent in view of the Tamura publication and the Nobuo reference. Claims 19 and 37 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Sarrine patent in view of the Hudson patent. Claims 20 and 38 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Sarrine patent in view of the Hudson patent and further in view of the Long patent. Claims 22 and 26 were rejected under 35 U.S.C. § 103(a) as being unpatentable over the Sarrine patent in view of the Anderson patent. Claims 23 was rejected under

35 U.S.C. § 103(a) as being unpatentable over the Sarrine patent in view of the Anderson patent and further in view of the Warren patent. Claims 39 was rejected under 35 U.S.C. § 103(a) as being unpatentable over the Sarrine patent in view of the Kercso patent.

Objections to the drawings and specification have also been made with respect to reference numerals and grammatical errors. Formality objections to the claim language are included as well. Corrected drawings and specification amendments were requested.

In reply to the Office Action, Applicant has extensively amended the independent claims so as to more accurately claim method and apparatus of the present invention. The independent method Claim 1 has been replaced by independent Claim 40, and the independent apparatus Claim 24 has been replaced by independent Claim 60. Specifically, the independent claims now incorporate the limitations of the sample plate and gel plate positioning throughout the process of the present invention. Also, the unique stacking arrangement and bottom mounting features are recited in the independent claims. The independent Claims are now distinguished from the prior art Sarrine patent such that the present invention is no longer anticipated nor made obvious by the prior art.

Applicant has also amended the drawings and specification to correct the formalities objected to by the Examiner.

With regard to the independent method Claim 40, the method now includes the limitations of the sample plate movement and gel plate movement. The starting positions and ending positions of the gel plate, as the method progresses, is now positively recited. Additionally, the remaining steps are also described in terms of the positioning of the gel plate at the various stages and how those positions related to each other. These limitations are not disclosed by the Sarrine patent. The gel plate of the prior art did not have the stacked relationship of the present sample plates and gel

plates, and the method of the prior art does not disclose nor make obvious the movement steps of the present invention. The particular arrangement of the stations and the lateral movement of the gel plate are not disclosed by the Sarrine patent nor made obvious by a combination with the Sarrine patent. The original dependent Claims 2-23 correspond to the new dependent claims 41-59. The subject matter of Claim 2 (stacking) was incorporated in the independent claim, the subject matter of Claims 22 and 23 (stacking and disposal) were incorporated into a single dependent claims, and the subject matter (single pipette and washing) of Claims 3-5 were incorporated into a single dependent claim.

With regard to independent apparatus Claim 60, the "means + function" language has been maintained with the addition of limitations related to the relative locations and structural inter-relationships between the physical elements of the apparatus. Specifically, the locations of the gel plate are positively recited and further described in terms of the spatial relationship to each other. The prior art references do not contain these limitations. The automated path of this particular device is not anticipated nor made obvious by the Sarrine patent or combinations therewith. In particular, the parallel relationship between sample plate and gel plate and the alignment of the different stations are not disclosed by the prior art. The original dependent Claims 25-39 correspond to the new dependent Claims 61-73. The subject matter of Claim 25 (stacking) was incorporated in the independent claim, and the subject matter of Claims 31 and 32 (washing) was incorporated into a single dependent claim.

Applicant notes that the prior art references cited against the present invention were provided by the Applicant and discussed in the specification. Applicant further notes the common ownership by the Assignee, Helena Laboratories, of multiple prior art patents used against the present invention

and the present invention itself. As such, Applicant respectfully maintains that the present invention is distinct from the prior art as previously acknowledged in the specification. Applicant is aware that the process of electrophoresis is generally well-known and established in the field. Applicant seeks protections of the specialized machine developed by the Applicant with specific innovations in the in situ environment with special automation, single pipette use, stacked plate arrangements, and gel plate conveyance through the stages of the electrophoresis process.

Based upon the foregoing analysis, Applicant contends that independent Claims 40 and 60 are now in proper condition for allowance. Additionally, those claims which are dependent upon these independent claims should also be in condition for allowance. Reconsideration of the rejections and allowance of the claims at an early date is earnestly solicited. Since no new claims have been added above those originally paid for, no additional fee is required.

Respectfully submitted,

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Paragraph [0020] should be amended as follows:

[0020] Initially, a plate holder is used to mount a gel plate for testing. The plate holder has a frame and electrodes. The mounted gel plate is moved from the mounted gel plate storage to the application station. A single pipette is provided so as to be in communication for loading with the wetting agent in the wetting agent container. The pipette is inserted into transfer hole in the electrophoresis station so as to apply the wetting agent onto the cooling plate of the electrophoresis chamber which is equipped with a cooling device. The mounted gel plate is then conveyed from the application station to ~~on~~ the cooling plate in the electrophoresis station.

Paragraph [0028] should be amended as follows:

[0028] In the present invention, the roller is also washed subsequent to the ~~of~~ staining. The washing of the roller involves the step of moving the roller to a roller wash station, lowering the roller so as to be submersed in water, and then rolling the roller over a blotter paper so as to release water from the roller and to dry the roller.

Paragraph [0029] should be amended as follows:

[0029] The present invention also involves the unique step of de-staining the dried mounted gel plate or the incubated mounted gel plate prior to the step of scanning. In those circumstances where de-staining is required, the stained mounted gel plate is moved from the drying or the incubating station to a washing station. The mounted gel plate is moved to the de-staining or washing station, wherein washing or fixing liquid is kept in the plate holder. As one end of the plate holder acts as a pivot,

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the plate holder is tilted at angle. A flow of washing or fixing liquid is then applied across the tilted mounted gel plate such that the flow of the washing or fixing liquid flows from the raised end of the mounted gel plate to the lowered end of the mounted gel plate. The surface of the mounted gel plate is suitably wiped so as to agitate the washing or fixing liquid flow across the surface of the tilted mounted gel plate. The de-stained mounted gel plate can then be leveled so as to ~~having~~ have a horizontal orientation. This de-stained gel plate can then be moved to a station for drying, and the de-stained mounted gel plate can be moved to the scanning station for analysis. In the present invention, the back side of mounted gel plate is also washed by flowing of the washing or fixing liquid between the plate holder and the back side of mounted gel plate.

Paragraph [0037] should be amended as follows:

[0037] In FIGURE 1, it can be seen that the very first step associated with the method of the present invention is the preparation of the sample plates, the mounted gel plates and the reagents. Initially, the manually loaded sample well plates are placed into the sample plate storage 10 located at the right side of the housing 2 of the automated electrophoresis apparatus 1. FIGURE 3 shows a top plan view of a sample plate F3, having numbered wells. This example of a sample plate may be used in the present invention. The mounted gel plates are loaded into the mounted gel plate storage 20 located on the opposite side of housing 2. FIGURES 2(a-c) show the structures of a mounted gel plate F2, comprised of a plate holder 200, electrodes 203 and a gel plate 210. The plate holder 200 protects the gel plate from evaporation when placed in the mounted gel plate storage 20, the electrophoresis chamber, the incubator and the de-staining compartment. The appropriate reagents

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used for the electrophoresis operation of the present invention are placed in the respective reagent reservoirs 40a-40f. Once the sample plates are loaded in the sample plate storage 10, the gel plates are loaded into the mounted gel plate storage 20 and the reagents are appropriately loaded, the automated electrophoresis apparatus 1 of the present invention will be able to carry out a large number of analyses in situ. As a result, contamination of samples is effectively avoided. Similarly, the human element associated with the manipulation of the electrophoresis analysis technique is avoided. The present invention carries out each of the steps in an automated manner so that the results can be displayed on the computer screen of computer 5 or printed out by printers 6.

Paragraph [0038] should be amended as follows:

[0038] The preparation of the sample plate F3 and the mounted gel plate F2 includes lowering the bottom 20a of the mounted gel plate storage 20 so as to release the mounted gel plate F2 selected for testing. The single selected mounted gel plate F2 is moved from the gel plate storage 20 to the application station 50. Similarly, a single sample plate F3 is moved from the waiting stock 14 in the sample plate storage 10 by transferring belt ~~100~~ 11. Before the transfer belt ~~100~~ 11 is operated, the bottom 13 of the finished stock 15 is lifted so as to make space for passing the sample plate F3 under the finished stock 15. Then, the single sample well plate F3 is transferred into the position of sample well plate holder 55 by transfer belt ~~100~~ 11.

Paragraph [0051] should be amended as follows:

[0051] The final step associated with the automatic electrophoresis operation of the present

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invention is the step of scanning. This step of scanning applies to either of the staining processes. Initially, the mounted gel plate is moved the scan station 100. Scan station 100 has a scanner, a dryer 105 and utilizes a fan and a heat source. The mounted gel plate will, at this time, be showing visible bands. The scan station 100 will include a scanner 102 to electronically analyze the visible bands in the gel. This analysis will involve ~~the~~ measuring to the location, intensity and resolution of the bands. The collected information including the gel plate number 211 printed on the gel plate will create a profile of bands so as to allow the identification of the sample. The method of analyzing the visible bands in the gel is described in greater detail in association with U.S. Patent Nos. 5,460,709 or 4,890,247, owned by the present assignee. The mounted gel plate is then moved to the mounted gel plate disposal unit 30. This mounted gel plate disposal unit 30 will collect and stack the mounted gel plates after the scanning process has occurred. The mounted gel plates will be stacked from the bottom to the top at the side of the base 3 opposite the mounted gel plate storage 20. The scanned information can be displayed on the computer terminal 5 or printed out by way of printer 6.

Paragraph [0052] should be amended as follows:

[0052] In the present invention it can be seen that the mounted gel plates will move in an automated manner across the base 3 of the automatic electrophoresis apparatus 1. With reference to FIGURE 5, the mounted gel plates are properly prepared on the left side of the base 3. These mounted gel plates will be passed through the various process until they are disposed on the right side of the base 3. The various other components of the automated electrophoresis apparatus will interact with these mounted gel plates as they move from station to station. The mounted gel plate is conveyed by the

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mounted gel plate carrier which is cached with both sides of the holder catcher 31. The cooling plate is lifted by moving the cooling plate lift 69 with the lifter 32 of the mounted gel plate carrier ~~30~~ 33. The heater 82 is also lifted by moving the heat block lift actuator 86 with the mounted gel plate carrier ~~30~~ 33.